PCT/GB 2003 / 001386

REC'D 2[illegible] APR 2003

WIPO PCT

INVESTOR IN PEOPLE

The Patent Office

The Patent Office
Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

In accordance with the rules, the words "public limited company" may be replaced by p.l.c., plc, P.L.C. or PLC.

Re-registration under the Companies Act does not constitute a new legal entity but merely subjects the company to certain additional company law rules.

PRIORITY DOCUMENT

SUBMITTED OR TRANSMITTED IN COMPLIANCE WITH RULE 17.1(a) OR (b)

Signed [illegible]

Dated 4 March 2003

Patents Form 1/77

Patents Act 1977
(Rule 16)

The Patent Office

23MAY02 E720171-1 D02882
P01/7700 0.00-0211851.1

1/77

THE PATENT OFFICE
B
22 MAY 2002
LONDON

Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

The Patent Office

Concept House
Cardiff Road
Newport
South Wales NP10 8QQ

1.	Your reference	60177/000
2.	Patent application number *(The Patent Office will fill in this part)* 0211851.1	22 MAY 2002
3.	Full name, address and postcode of the or of each applicant *(underline all surnames)*	BIOQUELL UK LIMITED Walworth Road Andover Hampshire SP10 5AA
	Patents ADP number *(if you know it)*	8079873001
	If the applicant is a corporate body, give the country/state of its incorporation	UK
4.	Title of the invention	IMPROVEMENTS IN OR RELATING TO APPARATUS FOR DECONTAMINATING ENCLOSED SPACES
5.	Name of your agent *(if you have one)*	BOULT WADE TENNANT
	"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*	VERULAM GARDENS 70 GRAY'S INN ROAD LONDON WC1X 8BT
	Patents ADP number *(if you know it)*	42001
6.	If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number	Country / Priority application number (if you know it) / Date of filing *(day/month/year)*
7.	If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application	Number of earlier application / Date of filing *(day / month / year)*
8.	Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if: a) any applicant named in part 3 is not an inventor, or b) there is an inventor who is not named as an applicant, or c) any named applicant is a corporate body. See note (d))*	Y

9. ~~Enter the number of sheets for any of the~~ following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	N
Description	9
Claim(s)	2
Abstract	
Drawing(s)	4 +4

10. If you are also filing any of the following, state ~~how many against each item~~

Priority documents	N
Translations of priority documents	N
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	N
Request for preliminary examination and search *(Patents Form 9/77)*	N
Request for substantive examination *(Patents Form 10/77)*	N
Any other documents *(Please specify)*	

11 I/We request the grant of a patent on the basis of this application.

Signature

Date 22 May 2002

12. Name and daytime telephone number of person to contact in the United Kingdom

Geoffrey C Bayliss
020 7430 7500

Warning

After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents ct 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

Notes

a) *If you need help to fill in this form or you have any questions, please contact the Patent Office on 01645 500505.*

b) *Write your answers in capital letters using black ink or you may type them.*

c) *If there is not enough space for all the relevant details on any part of this form, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s). Any continuation sheet should be attached to this form.*

d) *If you have answered 'Yes' Patents Form 7/77 will need to be filed.*

e) *Once you have filled in the form you must remember to sign and date it.*

f) *For details of the fee and ways to pay please contact the Patent Office.*

IMPROVEMENTS IN OR RELATING TO APPARATUS FOR DECONTAMINATING ENCLOSED SPACES

This invention relates to apparatus for decontaminating enclosed spaces such as hospital wards and clean rooms in which a manufacturing or other processes take place in sterile conditions. This application supplements the disclosure in our UK Patent Application No. 0207452.4 filed on 28 March 2002.

Vaporised aqueous solution of hydrogen peroxide has been used to decontaminate the internal surfaces of enclosures used for aseptic processing in the pharmaceutical industry since about 1990, but it has always been difficult to use the same technology to decontaminate larger volumes such as rooms.

The conventional design of the gas generator is a closed loop design such as described in US Patent 5,173,258. In this design the hydrogen peroxide and water vapours are produced by flash evaporation of an aqueous solution into a circulated heated air stream which carries the vapours to the space to be decontaminated. The air and hydrogen peroxide/water vapours mix with the air inside the chamber before being returned to the gas generator, where the gas is decomposed, dried, heated and more liquid is flash evaporated and the air mixture is re-circulated to the chamber.

The processes performed on the returned gas are complex, and include the steps of decomposing the gas, drying and re-heating. This complete process was considered necessary because it was thought that the hydrogen peroxide gas decomposed according to a half-life rule and hence to maintain an adequate

concentration inside the chamber a circulating system that decomposed the gas and added a fresh supply was thought to be necessary. Recent work by Watling, (ISPE Conference Zurich, September 1999) has shown that the gas does not decompose but is stable. It is therefore not necessary to remove the returning gas from the chamber.

S.S. Block reports in the 5th Edition of Disinfection, Sterilisation and Preservation page 189 that 3% hydrogen peroxide gives a log 8 reduction of Staphylococcus aureus in under 20 minutes. A much slower rate of deactivation has been found in experimental work when exposing Staphylococcus aureus to gas generated from 35% solution, despite the fact that the process was operated below the dew point. Under these gassing conditions the first droplets of dew form on the organism at a much higher concentration that the original liquid, typically about 65% w/w, the exact value depending on the moisture content of the carrier gas.

As stated above in the conventional system the air in the chamber to be decontaminated is dried prior to injecting the decontaminating gas. This is done to allow a high level of gas concentration to be achieved before the onset of condensation, or if it is desired to run the process dry. The vapour pressure equations for hydrogen peroxide may be used to calculate the concentration of the condensate when the solution is flash evaporated and passed into a chamber. If the RH in the chamber is high the condensation will form quickly but as a relatively weak solution. Evaporating 35%w/w hydrogen peroxide into a chamber at 20°C and 85% RH will cause the condensate to form at in excess of 6% w/w, although the concentration of the vapour will be about 120 ppm. It is well known that

6% hydrogen peroxide is active against microorganisms and will cause deactivation of surfaces. It is therefore not necessary to reduce the humidity in the chamber under normal operating conditions as the RH will be less than 85% and hence the condensation will form at a concentration greater than 6%.

It is believed that the difference between the liquid process as reported by Block and a gaseous dew process is the rate of delivery of the hydrogen peroxide condensation. It follows that using a standard recirculating gas generator placed outside the space to be decontaminated, there may not be an adequate evaporation capacity to achieve a sufficiently high condensation rate to deactivate the organism inside the chamber. The deactivation process may be enhanced by the use of mixtures of chemicals but the principal of the rate of delivery still remains.

An analysis of the equations governing the vapour pressure of water and hydrogen peroxide as published in 1955 in the American Chemical society monograph "Hydrogen Peroxide" and edited by W. Schuub, shows that the gas concentration inside a chamber may be raised to the dew point by flash evaporation, but as soon as the dew point is reached condensation will form at a higher concentration than the evaporated liquid thus reducing the gas concentration. The gas concentration will continue to fall as more liquid is evaporated until the equilibrium vapour pressure for the evaporated liquid is reached at the temperature of the chamber.

This invention provides an apparatus for decontaminating an enclosed space comprising a passageway having an air inlet at one end and an

outlet at the other end, means to cause a flow of air through the passageway from the inlet to the outlet, means to heat the air flowing through the passageway to a predetermined temperature, evaporator means in communication with the passageway, means to delivery liquid decontaminant from a supply of decontaminant to the evaporator means to be evaporated thereby and for the evaporant to be delivered to the air flow in the passage to flow in the air flow from the outlet to the rooms to be decontaminated.

By placing the gas generator inside the room and simply heating the carrier gas and then evaporating this sterilant into the air stream it is possible to use the available energy much more efficiently. The increase efficiency is derived from the removal of the system for decomposing and drying the carrier gas, and also because there is no need for any pipe work to transport the carrier gas and decontaminant from an external generator.

This increased efficiency provides more energy for the primary function of heating the carrier gas and flash evaporating the liquid. The efficiency increase is so great as it allows a trebling of the rate of flash evaporation from the same energy source and hence the achievable rate of formation of condensation once the dew point has been reached is also trebled.

The simplified design is also much smaller and lighter than a conventional gas generator and hence considerably less expensive to manufacture. It is therefore realistic to place a number of such devices inside a chamber to be decontaminated to ensure that the decontaminating vapours reach all surfaces of the chamber.

Each simplified generator may have its own control system, which is linked to a control box external to the room and connected by a single control cable.

The following is a description of some specific embodiments of the invention, reference being made to the accompanying drawings, in which:

Figure 1 is a wholly diagrammatic view of an apparatus for delivering an air flow containing an evaporated decontaminant to an enclosed space;

Figure 2 is a similar view to Figure 1 showing the components of the apparatus including the evaporator, liquid sterilant supply and outlet nozzle in greater detail;

Figure 3 is a perspective view of a practical working apparatus;

Figure 4 is a plan view of the evaporator; and

Figure 5 is a cross-sectional view on the line 5-5 of Figure 4.

The apparatus will be described firstly with reference to Figures 1 and 2. Room air, which may or may not already contain previously supplied hydrogen peroxide and water vapour, is drawn into an inlet conduit 10 through a HEPA filter 11 by a variable speed motor driven fan 12. The HEPA filter 11 removes any particles from the air stream to ensure that the delivered air is of the correct quality when the generator is used in a clean room. The conduit delivers the air to a heater 13 where the temperature is raised to a predetermined level as described below.

The heated air then passes into an evaporator 14 where a liquid sterilant is flash evaporated. It is possible to combine the heater 13 and the evaporator 14 into a single unit with a heating element as shown in Figure 2 to 5 to which reference will be made later. The physical shape and dimensions of the combined heater/evaporator are designed to control the energy balance between that used to heat the carrier gas and that used for flash evaporation.

A sterilant liquid is stored in a container 15 and is pumped to the evaporator 14 by a liquid pump 16. The carrier gas and vapours are delivered from the evaporator through a conduit 17 to a distribution nozzle 18 for delivery of the sterilant vapour to the space to be decontaminated.

As shown in Figure 3, the whole of the apparatus may be supported in an open tubular steel framework 19 for ease of movement. Ideally, the apparatus should not be placed inside a housing unit. Any covering of the apparatus would restrict the sterilant gas movements around and through the apparatus, which is essential to ensure that the apparatus itself is also surface decontaminated because otherwise it may contaminate the area in which it is placed.

An ideal decontamination cycle may have three distinct phases. In the first, optional phase the relative humidity in the room or other enclosure is adjusted to a pre-set level. In the second phase the gas concentration of sterilant gas is raised to form a required layer of overall surfaces in the enclosure condensation for a sufficient length of time to achieve the required level of decontamination. In the third and last phase the sterilant is removed from the enclosure.

In practice, the apparatus would be used in conjunction with other equipment. If a HVAC system is available for the chamber then this may be used to achieve the required level of relative humidity at the start of the process, and if the HVAC exhausts to a safe area to remove the sterilant at the end. Alternatively a portable dehumidifier may be used to adjust the initial relative humidity and a catalytic scrubber used to circulate the gas to remove the sterilant.

In the decontamination cycle referred to above the initial phase of treatment in the adjustment of the relative humidity in the room or chamber may be omitted and the process commenced at the current prevailing conditions in the enclosure since the relative humidity in the enclosure would normally be well below dew point and so a considerable amount of sterilant/water vapour would need to be generated in the enclosure before condensation would occur.

Reference is now made to Figures 4 and 5 which illustrate the combined heater/evaporator 14/15 in greater detail. The heater/evaporator comprises a cast cylindrical aluminium block 30 which is mounted framework 19 with the axis of the block extending vertically. The lower end of the block has a shallow cylindrical recess 31 and a circular base plate 32 is attached to the periphery of the block extending across the recess by screws (not shown) the base plate 32 has a central aperture 33 in which the end of the inlet conduit 10 is mounted to deliver a supply of air to the recess in the block.

The upper end of the block also has a cylindrical recess 34 and a central top plate 35 is mounted on the periphery of the block over the recess by set screws

36. The top plate 35 has a central aperture 39 in which an outlet conduit 40 from the block is mounted.

The block is formed with a central cylindrical cavity 37 extending into the block from the upper end thereof in which the outlet conduit 40 extends stopping short of the bottom of the cavity. The block 30 has a multiplicity of axially extending passageways 38 adjacent the outer surface of the block and spaced around the block leading from the lower recess 31 and the block upper recess 34 for flow of air from the bottom recess to the top recess from where the air can flow into the cavity 37 and thence into the outlet conduit 40. The liquid sterilant from the storage container 15 is delivered via one or more inlet conduits 41 which extend through the top plate 35 adjacent to the outlet conduit 40 and also lead into the cavity 37 in the block and again stop short of the bottom of the cavity. A second such inlet conduit 41 is shown in dotted outline and preferably three such conduits are provided at spaced locations around the inlet conduit.

The body 30 is encircled by a cylindrical jacket in which an electrical resistance heater 42 is mounted for heating the body 30 to a requisite temperature to pre-heat the airflow through the block and also to ensure that sterilant delivered by the conduit 14 to the bottom of the cavity 37 of the block is flash evaporated from the bottom of the cavity to produce a vapour which is entrained in the flow of air through the flow of heated air through the outlet conduit 40 for delivery into the room to be sterilised.

The heating unit of the heater-evaporator is coupled to the control unit to the apparatus and a temperature probe 44 is mounted in a radial drilling

45 in the body 30 below the cavity 37 to measure the temperature of the body for adjusting, through the control unit, the power supply to the resistance heating element to enable the body to be maintained at a requisite temperature for pre-heating the air flowing through the body and flash evaporating the sterilant delivered to the body.

1. An apparatus for decontaminating an enclosed space comprising a passageway having an air inlet at one end and an outlet at the other end, means to cause a flow of air through the passageway from the inlet to the outlet, means to heat the air flowing through the passageway to a predetermined temperature, evaporator means in communication with the passageway, means to delivery liquid decontaminant from a supply of decontaminant to the evaporator means to be evaporated thereby and for the evaporant to be delivered to the air flow in the passage to flow in the air flow from the outlet to the rooms to be decontaminated.

2. An apparatus as claimed in claim 1 wherein the outlet to the passage comprises one or more nozzles for directing air carrying evaporated decontaminant to selected regions of the room.

3. An apparatus as claimed in claim 1 or claim 2, wherein the means for heating the air also heats the decontaminant in the evaporator means to vaporise the decontaminant.

4. An apparatus as claimed in any of the preceding claims, wherein the means to deliver an air flow through the passageway comprise a fan located in the passageway adjacent the inlet thereof.

5. An apparatus as claimed in any of the preceding claims, wherein an air filter is included in the inlet to the passageway to remove articles from the air flowing into the passageway.

6. An apparatus as claimed in any of the preceding claims wherein the means to delivery liquid decontaminant to the evaporator means comprise a storage vessel for a supply of liquid decontaminant, a

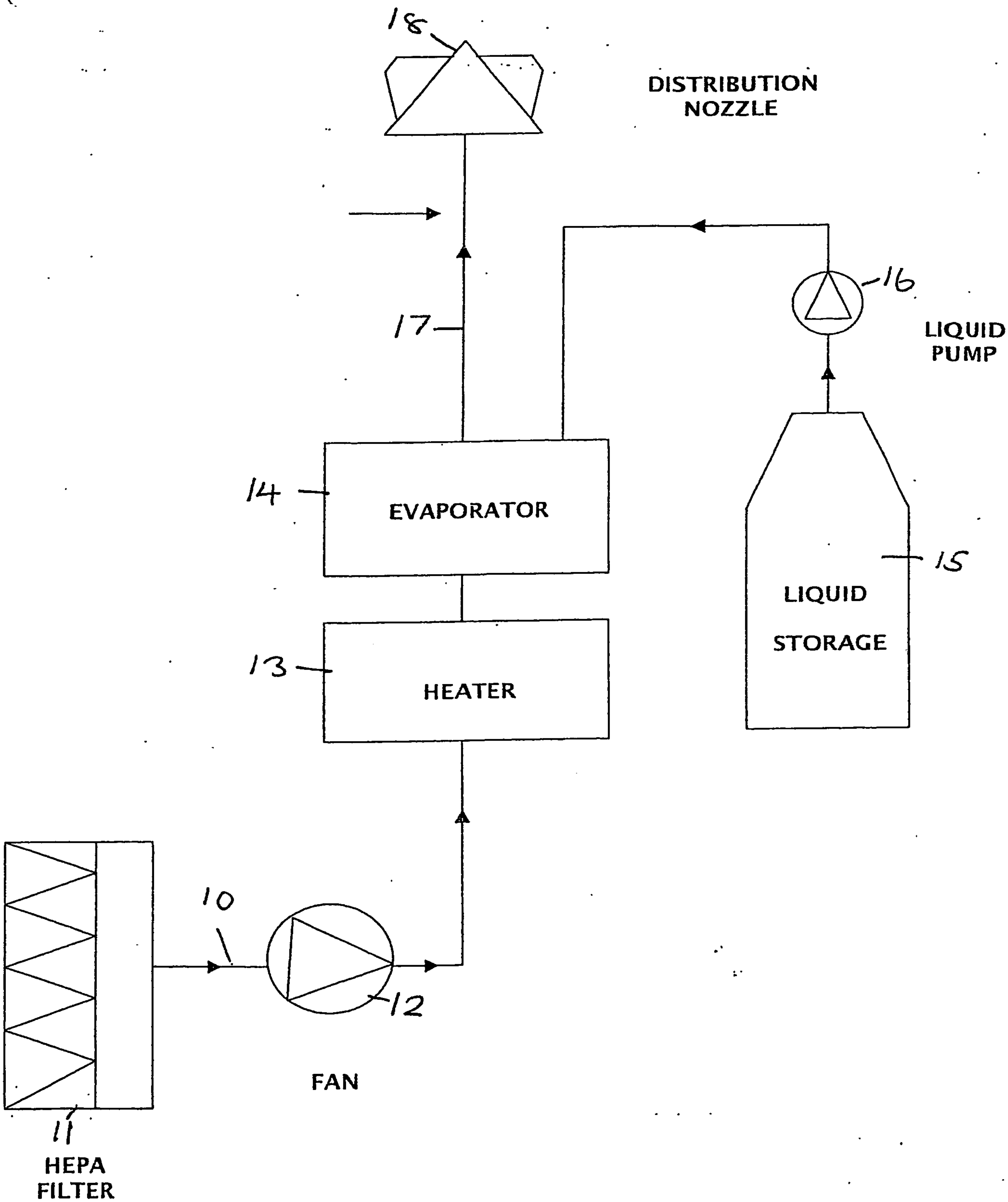
flow path between the vessel and the evaporator and pump means in the flow path for delivering liquid decontaminant from the vessel to the evaporator means.

7. An apparatus for decontaminating an enclosed space comprising a plurality of apparatus as claimed in any of the preceding claims with the outlets from the respective apparatus directed to different regions of the enclosed space.

8. An apparatus for decontaminating an enclosed space such as a room substantially as described with reference to and illustrated in the accompanying drawings.

V2 375773: GCB: CAR

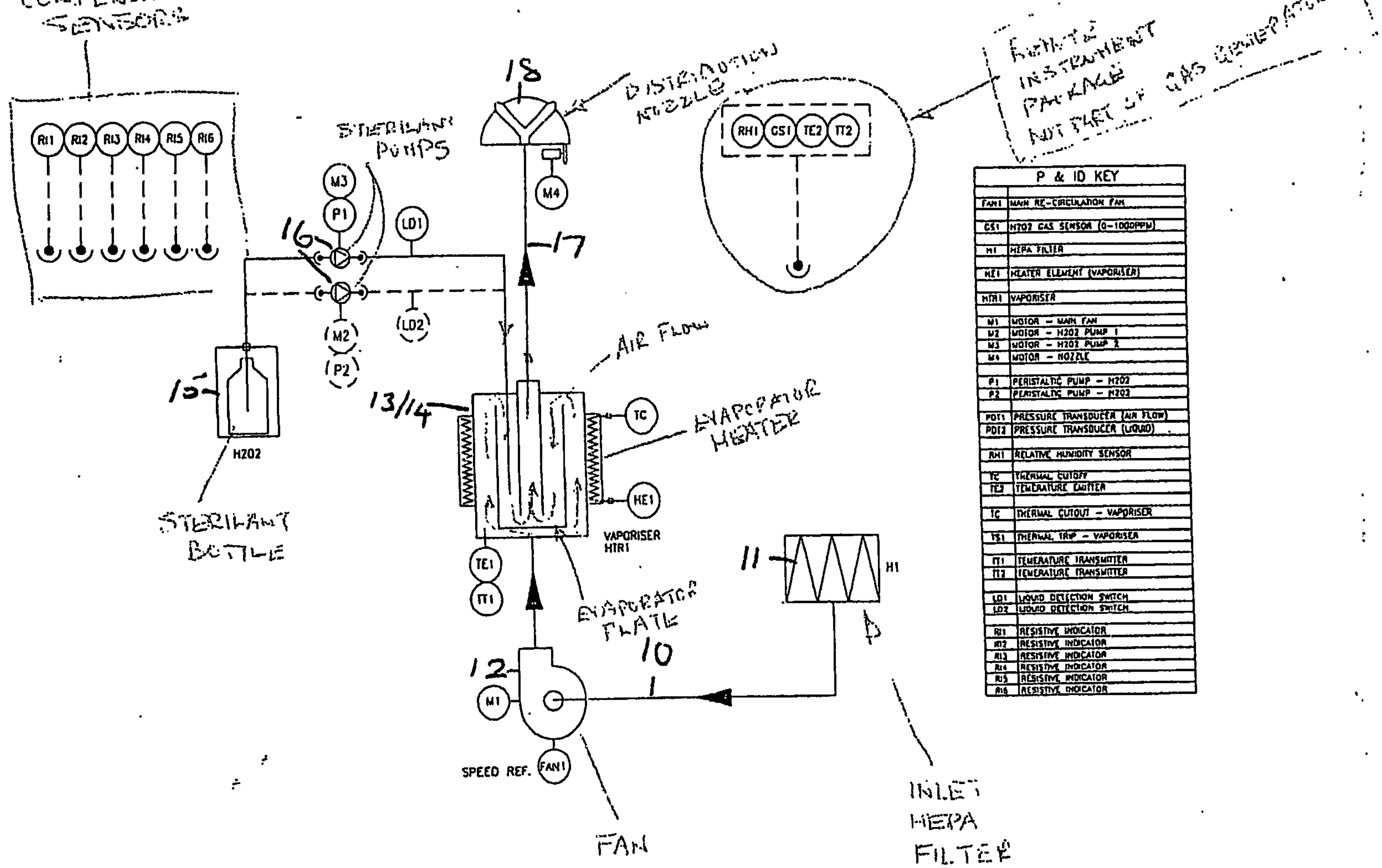
FIG. 1



BioQuell Pharma/DW/4/11/02

038-9000 | REV A

Fig 2



P & ID KEY	
FAN1	MAIN RE-CIRCULATION FAN
GS1	H2O2 GAS SENSOR (0-1000PPM)
H1	HEPA FILTER
HE1	HEATER ELEMENT (VAPORISER)
HTR1	VAPORISER
M1	MOTOR – MAIN FAN
M2	MOTOR – H2O2 PUMP 1
M3	MOTOR – H2O2 PUMP 2
M4	MOTOR – NOZZLE
P1	PERISTALTIC PUMP – H2O2
P2	PERISTALTIC PUMP – H2O2
PDT1	PRESSURE TRANSDUCER (AIR FLOW)
PDT2	PRESSURE TRANSDUCER (LIQUID)
RH1	RELATIVE HUMIDITY SENSOR
TC	THERMAL CUTOFF
TE2	TEMERATURE EMITTER
TC	THERMAL CUTOUT – VAPORISER
TS1	THERMAL TRIP – VAPORISER
TT1	TEMERATURE TRANSMITTER
TT2	TEMERATURE TRANSMITTER
LD1	LIQUID DETECTION SWITCH
LD2	LIQUID DETECTION SWITCH
RI1	RESISTIVE INDICATOR
RI2	RESISTIVE INDICATOR
RI3	RESISTIVE INDICATOR
RI4	RESISTIVE INDICATOR
RI5	RESISTIVE INDICATOR
RI6	RESISTIVE INDICATOR

DESCRIPTION | DRAWN | DATE | C.R No

THIS DRAWING HAS BEEN PRODUCED IN AUTOCAD

BIOQUELL pharma
Walworth Road, Andover, Hampshire
England. SP10 5AA
Tel 01264 835853 Fax 01264 835854
email: enquiries@bioquellpharma.co.uk

MATERIAL | SPECIFICATION
FINISH | SPECIFICATION
MASS | SCALE
PROJECTION 3rd ANGLE

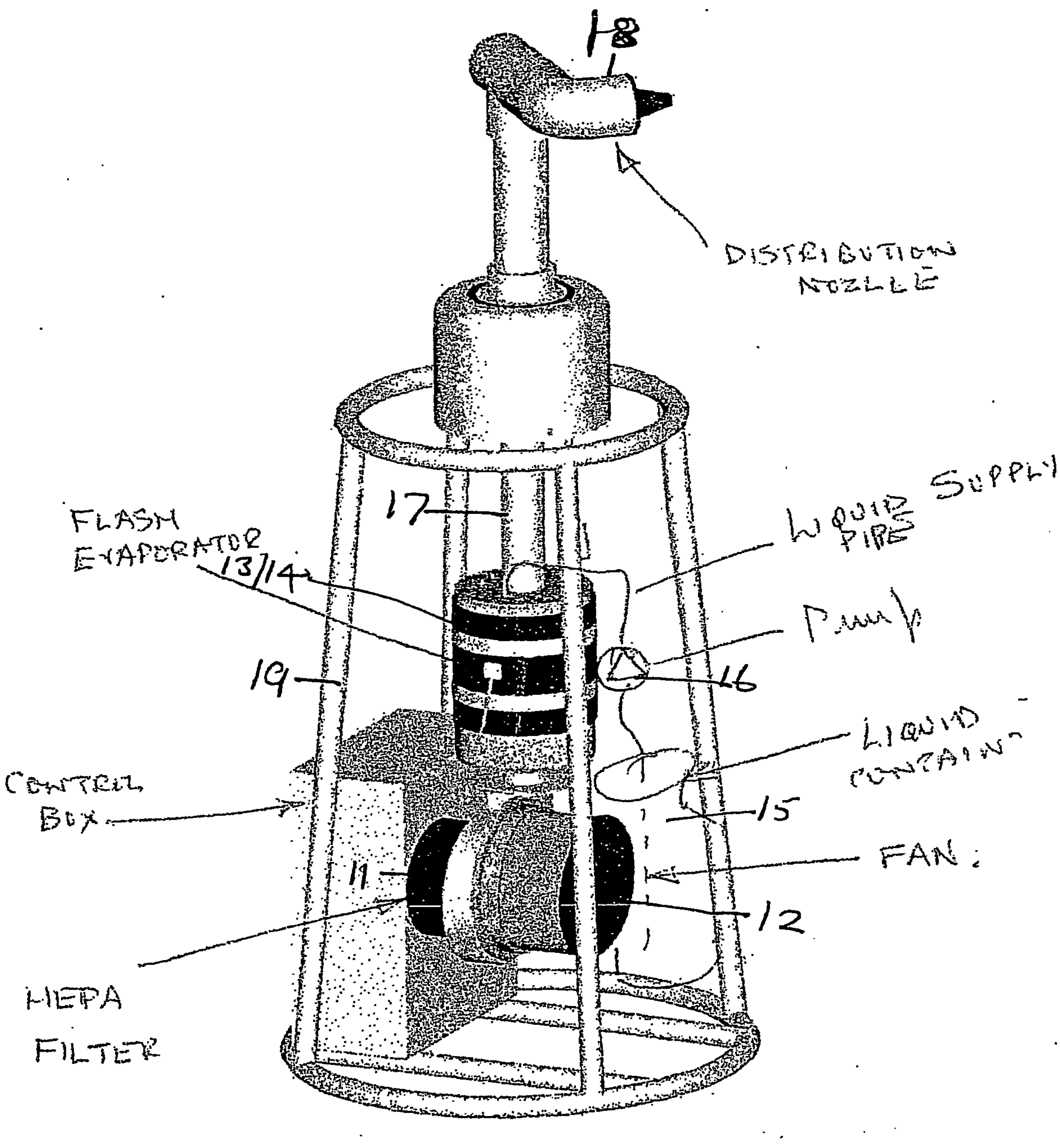
Drawing practices to be to BS308
All burrs and sharp edges to be removed
All dimensions in mm
DO NOT SCALE

SHEET TOLERANCE
1 = ± 1.0
1.0 = ± 0.5
1.00 = ± 0.25
ANG = ± 1.0°
MACHINED TOLERANCE
1 = ± 0.5
1.0 = ± 0.25
1.00 = ± 0.125
ANG = ± 0.25°
Unless otherwise stated

TITLE
CLARUS R P&ID

DRAWN | CHECKED | APPROVED DESIGN | DATE | SHEET 1 OF 1 | A1
APPROVED PRODUCTION | DRAWING No TD038-9000 | REV A

Fig 3


18
DISTRIBUTION
NOZZLE
17
FLASH
EVAPORATOR
13/14
LIQUID SUPPLY
PIPE
PUMP
16
19
LIQUID
CONTAIN
CONTROL
BOX
15
FAN
11
12
HEPA
FILTER

TD032-2101 B

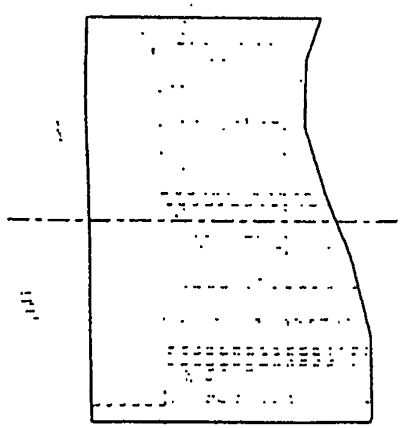


FIG 4

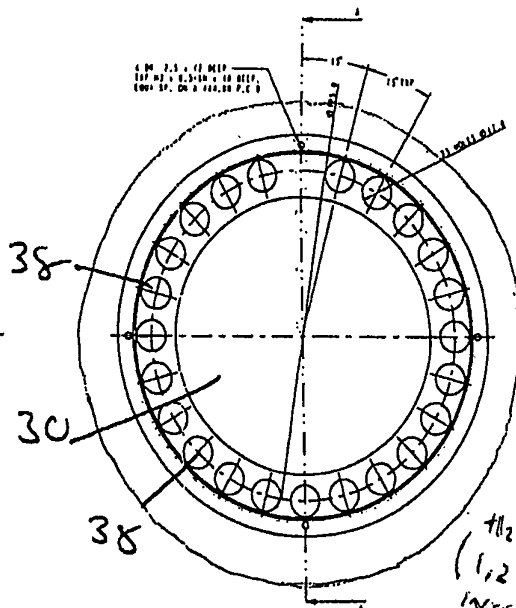
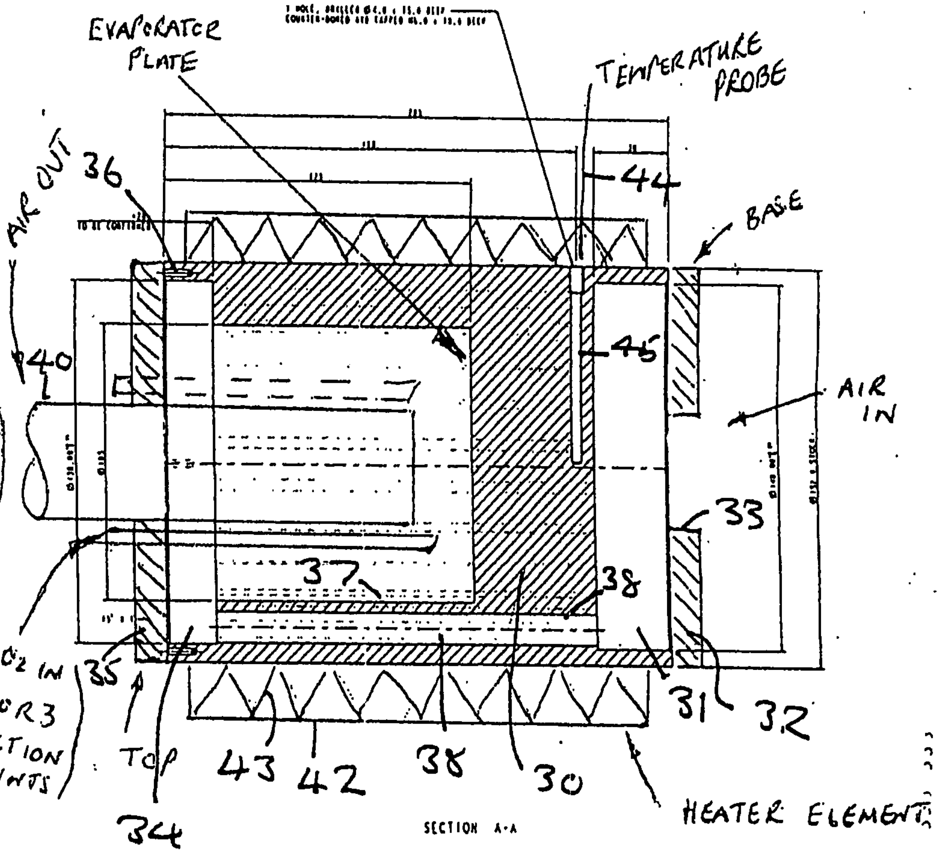


FIG 5



BIOQUELL pharma

MATERIAL: ALUMINIUM ALLOY

FINISH: CLEAR

SCALE: 1:1

TITLE: VAPOURISOR BODY

DRAWING No: TD032-2101

SHEET: A1

REV: B